DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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January 21, 2015

Lepu Medical Technology (Beijing) Co., Ltd.
C/O Arthur Goddard
Regulatory and Quality Systems Consultant
1531 Felton Road
South Euclid, Ohio 44121

Re: K141707
Trade/Device Name: ULTRASKIN™ Hydrophilic Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 18, 2014
Received: December 23, 2014

Dear Mr. Goddard,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): **K141707**

Device Name: ULTRASKIN™ Hydrophilic Guide Wire

Indications For Use:

The ULTRASKIN™ Hydrophilic Guide Wire is indicated to direct a catheter to the desired peripheral or coronary anatomical location during diagnostic or interventional procedure.

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510(k) Summary

The Summary of Safety and Effectiveness information on the ULTRASKIN™ Hydrophilic Guide Wire being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

I. SUBMITTER

Applicant:	Lepu Medical Technology (Beijing) Co., Ltd. No. 37 Chaoqian Road Changping District, Beijing 102200 P.R. China
Telephone:	+86-10-80123515
Contact:	Xiangdan Jin
Date:	June 20, 2014

II. DEVICE

Name:	ULTRASKIN™ Hydrophilic Guide Wire
Classification Name:	Catheter guide wire 870.1330
Regulatory Class:	Class II
Product Code:	DQX

III. PREDICATE DEVICE

Predicate:	Radifocus® Glidewire® Advantage, Terumo Corporation, K063372 with market clearance dates of Jan.19, 2007.
	No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Description:	The ULTRASKIN™ Hydrophilic Guide Wire consists of a Nitinol core wire, a plastic jacket with hydrophilic coating. The wire distal curve comes in different shapes such as straight, J angled and angled. The guide wire is radiopactitive under fluoroscopy.

V. INDICATION FOR USE

Intended Use:	The ULTRASKIN™ Hydrophilic Guide Wire is indicated to direct a catheter to the desired peripheral or coronary anatomical location during diagnostic or interventional procedure.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTIC WITH PREDICATE DEVICE

Substantial Equivalency Information:	The information provided in this submission, comparing intended use, principle of operation and performance, the ULTRASKIN™ Hydrophilic Guide Wire device is substantially equivalent to existing legally marketed device.

Section 5: 510(k) Summary

VII. PERFORMACE DATA

Biocompatibility: The ULTRASKIN™ Hydrophilic Guide Wire produced by Lepu Medical was assessed against the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The ULTRASKIN™ Hydrophilic Guide Wire would be classified as an External Communicating Device in contact with the Circulating Blood for a Limited Duration (<24 hours). The following test would be required for any patient / user contacting material:

Test	Standard	Results
Cytotoxicity	ISO 10993-5	The test article extract showed no evidence of causing cell lysis or toxicity
Maximum Sensitization	ISO 10993-10	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
Intracutaneous Irritation	ISO 10993-10	The test article met the requirements for the SC and SO test extracts.
Systemic Toxicity	ISO 10993-11	There was no mortality or evidence of systemic toxicity from the extracts injected into mice.
Haemolysis	ISO 10993-4	Both the test article in direct contact with blood and the test article extract were non-hemolytic.
USP Pyrogen Study	ISO 10993-11	The test article was judged as nonpyrogenic.
In Vivo Thromboresistance	ISO 10993-4	The test article and control were thromboresistant and comparable.
Partial Thromboplastin Time	ISO 10993-4	The test article would be considered a minimal activator and met the requirements of the test.
C3a Complement Activation Assay	ISO 10993-4	The test article was not considered to be a potential activator of the complement system.
SC5b-9 Complement Activation Assay	ISO 10993-4	The test article was not considered to be a potential activator of the complement system.

Sterilization: The method used is based on practices recommended by AAMI / ANSI / ISO 11135:2007 and provides a Sterility Assurance Level (SAL) of 10^{-6}

Shelf Life: In accordance with ISO 11070 the real time aging of ULTRASKIN™ Hydrophilic Guide Wire demonstrated that the performance of the specific components met the standard requirements without any significant difference to product performance requirements before aging. So the product is stable and reliable within the two-year useful life.

Section 5: 510(k) Summary

VII. PERFORMACE DATA, continue

Performance Testing: The ULTRASKIN™ Hydrophilic Guide Wire successfully passed all of the following performance tests:

ULTRASKIN™ Hydrophilic Guide Wire Performance Testing
Dimension Verification
Corrosion resistance
Fracture
Flexing test
Tensile strength
Torque strength
Torqueability
Tip flexibility
Coating integrity and particulate evaluation
Appearance
Chemical performance
Radiodetectability

Materials Comparison: The ULTRASKIN™ Hydrophilic Guide Wire materials have been subjected to biocompatibility tests and the differences between the Radifocus® Glidewire® Advantage (K063372), do not raise any new issues of safety or effectiveness.

Components	Radifocus® Glidewire® Advantage	ULTRASKIN™
Core Wire	Nitinol	Nitinol
Plastic Jacket	Polyurethane	Polyurethane, Wolfram Carbide
Coating	Hydrophilic coating	Hydrophilic coating

VIII. CONCLUSION

Conclusion: The information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the ULTRASKIN™ Hydrophilic Guide Wire supports a determination of substantially equivalent to existing legally marketed predicate device Radifocus® Glidewire® Advantage (K063372). Any technological differences between the ULTRASKIN™ Hydrophilic Guide Wire and the predicate device Radifocus® Glidewire® Advantage (K063372) do not raise new questions of safety or effectiveness.